IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To: *Converse v. Johnson & Johnson* No. 3:18-cv-17586-MAS-RLS *Newsome v. Johnson & Johnson* No. 3:18-cv-17146-MAS-RLS *Rausa v. Johnson & Johnson* No. 3:20-cv-02947-MAS-RLS	

DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT, LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DR. DANIEL CLARKE-PEARSON

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Five years ago, Dr. Daniel Clarke-Pearson candidly testified that it is impossible to know the cause of a woman's ovarian cancer absent a genetic mutation. Now, Dr. Clarke-Pearson seeks to offer a starkly different opinion: not only that he can tell what caused a woman's cancer, but that any time a woman used talc, it contributed to her cancer causation—and that it did so by 42 percent for regular talc users. Dr. Clarke-Pearson takes this position even though he cannot point to any scientific literature supporting these opinions and even though plaintiffs' own epidemiologist explained at his deposition that Dr. Clarke-Pearson's opinions are based on a mathematical fallacy: the conflation of increased risk and attributable risk.[1]

Based on this fallacy, Dr. Clarke-Pearson seeks to testify that talc was 42 percent responsible for Ms. Rausa, Ms. Converse and Ms. Newsome's cancers. While Dr. Clarke-Pearson purports to have employed a "differential diagnosis" in reaching these specific causation opinions, in truth he used no methodology at all—and instead simply assumed that talc exposure is a "cause" of ovarian cancer in any woman who claims to have used the product.

To the extent Dr. Clarke-Pearson's process can be characterized as a differential diagnosis, it was unreliable for multiple reasons.

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[1] Judge Wolfson's *Daubert* ruling only addressed general causation issues and therefore did not address the arguments in this motion.

First, Dr. Clarke-Pearson did not properly "rule in" talc as a possible cause of any plaintiff's cancer. While Dr. Clarke-Pearson asserts that talc can be "ruled in" as a cause of ovarian cancer in any woman who used the product, he ignores that the plaintiffs at issue have different subtypes of ovarian cancer, none of which has been significantly associated with talc use in the scientific literature; indeed, the scientific literature on clear cell carcinoma—the subtype with which Ms. Converse was diagnosed—shows no association with talcum powder use. Nor did Dr. Clarke-Pearson adequately consider other aspects of the plaintiffs' medical histories that disqualify talc use as a potential cause of their injuries, such as Ms. Rausa's [redacted] that closed the "pathway" by which talc purportedly reaches the ovaries more than 30 years before her ovarian cancer diagnosis.

Second, Dr. Clarke-Pearson's purported differential diagnosis also fails to properly "rule out" other potential causes of the plaintiffs' cancers. For example, Dr. Clarke-Pearson failed to rule out Ms. Converse's [redacted] use as causes of her clear cell carcinoma. This omission is shocking because women (like Ms. Converse) with [redacted] have a ***ten-fold increased risk of clear cell ovarian cancer***. Dr. Clarke-Pearson similarly failed to rule out Ms. Rausa's other known risk factors for ovarian cancer, including age, [redacted]. This

is notable because Ms. Rausa's history of [redacted] alone has been shown in some scientific literature to nearly double an individual's risk of ovarian cancer. And Dr. Clarke-Pearson similarly fails to rule out Ms. Newsome's [redacted], age and [redacted] as causes of her endometrioid carcinoma. This even though women (like Ms. Newsome) with [redacted] have a four-fold increased risk of endometrioid carcinoma, and obesity increases a woman's risk of developing endometrioid carcinoma by 37 percent.

Instead of ruling out any of these significant risk factors, Dr. Clarke-Pearson suggests that all risk factors somehow work together to cause a woman's ovarian cancer. But this hypothesis has no basis because Dr. Clarke-Pearson cannot cite any literature suggesting that different risk factors work synergistically to cause the genetic mutations that lead to ovarian cancer. Dr. Clarke-Pearson also ignores the distinct possibility that each plaintiff's cancer, like most cancers, is idiopathic. As a result, the only possible outcome of Dr. Clarke-Pearson's "differential diagnoses" was the finding he was hired to reach—that each plaintiff's ovarian cancer was caused by her exposure to talc. Such an approach does not meet the requirements for expert admissibility under Rule 702.

BACKGROUND

Dr. Clarke-Pearson is a gynecologic oncologist who has not treated patients since March 2020.[2] Dr. Clarke-Pearson has admitted that he has never told any patient—or any of the residents he trains—that he believes talc is a risk factor for ovarian cancer.[3] Nevertheless, Dr. Clarke-Pearson seeks to testify that each plaintiff's alleged "long-term use of Johnson's Baby Powder . . . is a substantial contributing cause" of her ovarian cancer because high-grade serous carcinoma (the most common subtype of epithelial ovarian cancer), clear cell carcinoma (a rare subtype of epithelial ovarian cancer), and endometrioid carcinoma have all purportedly been "associated with genital talcum powder use in multiple studies."[4] Dr. Clarke-Pearson asserts that these specific causation opinions are based on a

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[2] (Dep. of Daniel L. Clarke-Pearson ("1/17/24 Clarke-Pearson Dep.") 36:4-16, Jan. 17, 2024 (Ex. 1 to Decl. of Jessica Davidson ("Davidson Decl.")).)

[3] (1/17/24 Clarke-Pearson Dep. 38:13-39:3.)

[4] (2d Am. Rep. of Daniel L. Clarke-Pearson Re: Pasqualina Rausa ("Rausa Rep.") at 18, May 28, 2024 (Ex. 2 to Davidson Decl.); 2d Am. Rep. of Daniel L. Clarke-Pearson Re: Hilary Converse ("Converse Rep.") at 17, May 28, 2024 (Ex. 3 to Davidson Decl.); 2d Am. Rep. of Daniel L. Clarke-Pearson Re: Tamara Newsome ("Newsome Rep.") at 18, May 28, 2024 (Ex. 4 to Davidson Decl.).)

"differential diagnosis" methodology, which he describes as "start[ing] with all the possibilities and then try[ing] to focus and establish a diagnosis."[5]

Dr. Clarke-Pearson has previously admitted that he is unable to determine "that but for [a plaintiff's] talc use, [she] never would have gotten ovarian cancer"[6] and that "not all women who use[] talcum powder . . . get ovarian cancer."[7] According to Dr. Clarke-Pearson, however, "every woman who uses talc and gets ovarian cancer has talc as one of the causes of her ovarian cancer."[8] Specifically, Dr. Clarke-Pearson seeks to opine that the alleged "frequent" use of talc increases an individual's risk of ovarian cancer—regardless of what subtype of ovarian cancer or protective factors she has—by 42 percent.[9] Dr. Clarke-Pearson had initially opined that plaintiffs' talc usage increased their ovarian cancer risk by 30 percent, but in the middle of his most recent deposition, he changed that testimony and claimed that "it just came to [him]" in a restroom break that "these three

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5 (Dep. of Daniel L. Clarke-Pearson ("3/8/24 Clarke-Pearson Dep.") 374:10-375:4, Mar. 8, 2024 (Ex. 5 to Davidson Decl.).)

6 (Dep. of Daniel L. Clarke-Pearson ("8/26/21 Clarke-Pearson Dep.") 248:21-249:2, Aug. 26, 2021 (Ex. 6 to Davidson Decl.).)

7 (8/26/21 Clarke-Pearson Dep. 222:20-223:4.)

8 (*Id.* 238:2-14.)

9 (3/8/24 Clarke-Pearson Dep. 335:7-24; *id.* 336:10-17 ("Ms. Rausa's ovarian cancer has a 42 percent attribution to talc use."); *see also id.* 332:22-333:3 (talc use contributed 42 percent to Ms. Converse's clear cell ovarian cancer).)

women have used talcum powder extensively" "[a]nd the epidemiologic data says the extensive use does increase the risk by more than 30 percent."[10]

According to Dr. Clarke-Pearson, he belatedly arrived at his new opinion that talc use increases the risk of cancer by 42 percent based on a table in a 2018 article,[11] which pools studies examining whether a connection exists between perineal talc usage and ovarian cancer, and finds an odds ratio of 1.42 for frequent use of talcum powder.[12] This opinion, however, reflects either a fundamental misunderstanding of math or a deliberate misinterpretation because an increased risk of 42 percent is not the same as contributing 42 percent to a patient's disease.[13]

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[10] (*Id.* 328:23-329:9; *see also id.* 328:12-17 ("Q. So you've been on this case for five years and it came to the mind at the last break that you wanted to change your opinion? [A.] Yes.") (objection omitted).)

[11] Penninkilampi & Eslick, *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29(1) Epidemiology 41, 44 (2018) ("Penninkilampi 2018") (Ex. 7 to Davidson Decl.).

[12] (3/8/24 Clarke-Pearson Dep. 337:8-18.)

[13] (*See id.* 335:9-24 (Dr. Clarke-Pearson agreeing that "increasing your risk by 42 percent does not mean" "you're attributing 42 percent of the cause to something"); *see also* Dep. of Jack Siemiatycki ("3/27/24 Siemiatycki Dep.") 59:10-60:10, Mar. 27, 2024 (Ex. 8 to Davidson Decl.) (explaining that "[t]he relative risk of 1.47 means that for a woman who was a frequent user, her chance of developing ovarian cancer was 1.47 times greater than the risk for a non user," not that 47 percent of the woman's cancer causation should be attributed to perineal talc exposure)

Dr. Clarke-Pearson also concedes that each of the plaintiffs at issue has a number of risk factors unrelated to talc use that could have contributed to her ovarian cancer.[14]

Ms. Converse, who was diagnosed with clear cell carcinoma:

- had [redacted] and her "tumor arose in an [redacted] background";[15]
- had a first-degree relative, her mother, who was diagnosed with [redacted];[16]
- took [redacted] for ten years; and[17]
- had an [redacted] of "undetermined significance."[18]

Ms. Rausa, who was diagnosed with high-grade serous ovarian cancer:

- was 63 at the age of her diagnosis, which is "average age for a woman developing ovarian cancer";[19]

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14 (*See* Rausa Rep. at 19; Converse Rep. at 18; Newsome Rep. at 18-19.)

15 (Dep. of Peter Schwartz ("1/28/21 Schwartz Dep.") 31:19-32:4, Jan. 28, 2021 (Ex. 9 to Davidson Decl.) (pathology report stated her "tumor arose in an [redacted] background"); 8/26/21 Clarke-Pearson Dep. 366:13-22 (Dr. Clarke-Pearson agreeing that Ms. Converse's treating physician "believed it's likely her tumor arose in an [redacted] background").)

16 (Converse Rep. at 18.)

17 (*Id.*; 8/26/21 Clarke-Pearson Dep. 341:10-15.)

18 (Converse Rep. at 18; *see also* CONVERSE_HILARY_DRPETER SCHWARTZ_00008 (Ex. 10 to Davidson Decl.).)

19 (Rausa Rep. at 19.)

- had [redacted];[20]
- had a BMI of [redacted] at the time of her diagnosis, which qualifies as [redacted];[21]
- testified that she "underwent [redacted] which is above the average age";[22]
- had evidence of [redacted];[23] and

had a history of [redacted].[24]

And Ms. Newsome, who was diagnosed with endometrioid carcinoma:

- had first-degree relatives, her [redacted] and [redacted], who were diagnosed with [redacted];[25]
- had "a [redacted]"[26]
- had evidence of [redacted];[27]

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20 (*Id.*)

21 (*Id.*) Dr. Clarke-Pearson considers obesity to be a risk factor for ovarian cancer generally (8/26/21 Clarke-Pearson Dep. 165:6-166:7) and contends Ms. Rausa's BMI of [redacted] was "[a] cause" of her high-grade serous ovarian cancer (Dep. of Daniel L. Clarke-Pearson ("8/27/21 Clarke-Pearson Dep.") 662:15-22, Aug. 27, 2021 (Ex. 11 to Davidson Decl.); *see also id.* 675:17-676:2 (obesity "contributed to the outcome of ovarian cancer")). Dr. Clarke-Pearson fails, however, to cite any literature identifying obesity as a risk factor for high-grade serous ovarian cancer specifically.

22 (Rausa Rep. at 19.)

23 (8/27/21 Clarke-Pearson Dep. 665:21-666:17.)

24 (*Id.* 675:11-15; *see also* RausaP-DUHSMR-00003 (Ex. 12 to Davidson Decl.).)

25 (*See* NEWSOMET_AAMC_C_MDR000295 (Ex. 13 to Davidson Decl.).)

26 (Newsome Rep. at 18.)

27 (NewsomeT-WHSMR-00017 (Ex. 14 to Davidson Decl.).)

- was "[i]ncreasing [in] age";[28] and
- had a BMI over [redacted] at the time of her cancer diagnosis, which qualifies as [redacted].[29]

Ms. Converse and Ms. Newsome's risks with respect to [redacted] are particularly noteworthy because a population-based study of women with surgically verified endometriosis found that endometriosis was strongly associated with both clear cell ovarian cancer (OR 10.1 (CI = 5.50-16.9)) and endometrioid cancer (OR 4.72 (CI = 2.75-7.56)).[30] These results were confirmed in a study published just this month, which reported even stronger associations between endometriosis and both clear cell ovarian cancer (OR 11.15 (CI = 6.19-20.10)) and endometrioid cancer (OR 7.96 (CI = 5.59-11.34)) relative to women without endometriosis.[31] In other words, endometriosis, on its own, has been found to be associated with a ***ten-fold*** increased risk of clear cell carcinoma and at least a ***four-fold*** increased risk of endometrioid carcinoma.

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28 (8/27/21 Clarke-Pearson Dep. 590:9-14.)

29 (*Id.* 607:15-608:8; 3/8/24 Clarke-Pearson Dep. 313:6-15.)

30 Saavalainen, *Risk of Gynecologic Cancer According to the Type of Endometriosis*, 131(6) Obstet. & Gynecol. 1095, 1095 (2018) ("Saavalainen 2018") (Ex. 15 to Davidson Decl.); *see also* Noli, *Long Term Survival of Ovarian Endometriosis Associated Clear Cell and Endometrioid Ovarian Cancers*, 23(2) Int'l J. Gynecol. Cancer 244 (2013) ("Noli 2013") (Ex. 16 to Davidson Decl.).

31 Barnard, *Endometriosis Typology and Ovarian Cancer Risk*, JAMA (2024), at E3 tbl. 2 ("Barnard 2024") (Ex. 17 to Davidson Decl.).

Dr. Clarke-Pearson testified that ovarian cancer is "multifactorial" and therefore "it's very difficult for anybody to specifically say one thing," including talc, "caused ovarian cancer."[32] Indeed, according to Dr. Clarke-Pearson, "talcum powder, as a single factor" is not "enough to cause ovarian cancer."[33] Thus, instead of affirmatively ruling out ***any*** of the potential causes of Ms. Rausa's, Ms. Converse's, or Ms. Newsome's cancer, Dr. Clarke-Pearson claims that "[t]here are multiple things that cause ovarian cancer when they come together as a multifactorial impact on that ovarian tissue that becomes malignant."[34] Specifically, Dr. Clarke-Pearson opines that Ms. Rausa's "age, talc [use], [redacted], [redacted] and unknown factors all caused Ms. Rausa's ovarian cancer."[35] Similarly, Dr. Clarke-Pearson opines that Ms. Converse's [redacted] was a cause of her ovarian cancer.[36] And Dr. Clarke-Pearson opines that Ms. Newsome's "[i]ncreasing age" and [redacted] contributed to her developing

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32 (8/26/21 Clarke-Pearson Dep. 216:25-217:7; *see also id.* 255:6-18 ("[A.] I think that's a basic principle in oncology, that it's not just one mutation that causes a cancer, it's multiple. And that with epithelial types of cancers, it's propositioned . . . that they're multiple mutations, somewhere between, usually expected about 5 to 10 mutations.").)

33 (*Id.* 254:14-17.)

34 (*Id.* 249:14-17.)

35 (8/27/21 Clarke-Pearson Dep. 675:17-676:2.)

36 (*Id.* 460:13-16, 470:20-22.)

ovarian cancer.[37] Dr. Clarke-Pearson testified as such even though he admits that he is not "familiar with any literature suggesting that talc works synergistically with other risk factors to cause ovarian cancer."[38]

ARGUMENT

The standard for the admissibility of expert evidence under Amended Fed. R. Evid. 702 is set forth in Defendants' General Causation *Daubert* brief and incorporated herein. Dr. Clarke-Pearson's specific causation opinions do not satisfy this standard.

It is well recognized that "[a]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis." *Storey v. Transformhealthrx, Inc*., No. 415-149, 2024 WL 695410, at *7 (S.D. Ga. Feb. 20, 2024) (quoting *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005)); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010) ("Simply claiming that an expert used the 'differential diagnosis' method is not some incantation that opens the *Daubert* gate.") (citation omitted). Instead, a differential diagnosis must be conducted in a reliable manner, by reliably "rul[ing] in" the specific cause of a plaintiff's injuries and "rul[ing] out" other possible causes. *Ervin v. Johnson & Johnson, Inc.*, 492

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37 (*Id.* 590:9-14 (age); 3/8/24 Clarke-Pearson Dep. 321:3-12 (obesity).)

38 (3/8/24 Clarke-Pearson Dep. 274:6-10.)

F.3d 901, 904-05 (7th Cir. 2007) (noting that "expert opinions employing differential diagnosis must be based on scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out'"); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 609 (D.N.J. 2002) (a specific causation expert must generally "determin[e] the possible causes for the patient's symptoms and then eliminat[e] each of these potential causes until reaching one that cannot be ruled out"), *aff'd*, 68 F. App'x 356 (3d Cir. 2003).

While Dr. Clarke-Pearson purports to base his specific causation opinions on a "differential diagnosis," he did not employ that methodology. Instead, he simply assumed that talcum powder is a cause of ovarian cancer in any woman with the disease who reports using the product. Further, Dr. Clarke-Pearson failed to reliably: (1) rule in talc as a potential cause of any of the plaintiffs' different subtypes of ovarian cancer, particularly given their particular medical histories; or (2) rule out the different plaintiffs' other potential risk factors for ovarian cancer. As a result, Dr. Clarke-Pearson's specific causation opinions should be excluded.

I. DR. CLARKE-PEARSON DID NOT BASE HIS SPECIFIC CAUSATION OPINIONS ON A DIFFERENTIAL DIAGNOSIS.

Dr. Clarke-Pearson's specific causation opinion is not rooted in any methodology. Instead, Dr. Clarke-Pearson testified that "every woman who uses

talc and gets ovarian cancer has talc as one of the causes of her ovarian cancer."[39] Dr. Clarke-Pearson asserts that this is so because ovarian cancer has been "associated" with talcum powder use in the scientific literature.[40] Specifically, Dr. Clarke-Pearson takes the position that because the Penninkilampi 2018 meta-analysis reported an odds ratio between talc use and ovarian cancer of 1.42 for frequent talc use, this means that any ovarian cancer in any frequent talc user "has a 42 percent attribution to talc use."[41] This opinion fails Rule 702 for two reasons. First, it is not based in any methodology, and second, it is instead based on a mathematical fallacy.

Courts have repeatedly rejected specific causation opinions, like Dr. Clarke-Pearson's, that are based merely on a finding of an association between exposure and injury in the scientific literature. As these courts have recognized, a specific causation opinion based solely on an association in the literature amounts to an "unreliable speculative leap." *See, e.g.*, *Pugh v. Cmty. Health Sys., Inc*., No. 20-00630, 2023 WL 3361166, at *14 (E.D. Pa. May 10, 2023) ("Without additional

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39 (8/26/21 Clarke-Pearson Dep. 238:2-14; *see also id.* 241:9-16 ("[Q]. [I]f any woman says she used talcum powder and then she develops ovarian cancer, you are of the view that talcum powder was a cause of her ovarian cancer, right? [A.] A contributing cause of her ovarian cancer.") (objection omitted).)

40 (*See, e.g.*, Rausa Rep. at 18.)

41 (3/8/24 Clarke-Pearson Dep. 336:10-17 ("Q. And [you] believe Ms. Rausa's ovarian cancer has a 42 percent attribution to talc use? A. Yes."); *id.* 332:22-333:1 (same for Ms. Converse); *id.* 333:14-19 (same for Ms. Newsome).)

support and explanation, Dr. Mulkey's specific causation opinion based on her finding of a mere association between factors amount[s] to an unreliable 'speculative leap.'") (citation omitted); *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 1871, 2011 WL 135017, at *4-5 (E.D. Pa. Jan. 13, 2011) (excluding specific causation opinion that was "largely based upon studies showing an increased risk of cardiovascular mortality and myocardial infarctions for patients taking Avandia" because it relied on "an improper inferential leap from general causation to specific causation . . . without any evidence to show that Avandia caused or even contributed to" the plaintiff's alleged injury).

Dr. Clarke-Pearson's opinions are not just speculative, however; they are also based on a fundamental misunderstanding of math. Absolute risk (i.e., the likelihood of an event occurring) and relative risk (i.e., the likelihood of an event occurring in a group of people compared to another group of people in different environments) are not synonymous. As plaintiffs' own expert, Dr. Siemiatycki, explained at this deposition, a risk ratio reported in a meta-analysis (like Penninkilampi 2018), cannot "be turned into an absolute risk such that you can say that 4[2] percent of this woman's cancer causation relates to . . . perineal talc exposure" because "[t]he relative risk of 1.4[2] means that for a woman who was a

frequent user, her chance of developing ovarian cancer was 1.4[2] times greater than the risk for a non user."[42]

The figure below illustrates this principle. According to the current literature, "[a] woman's risk of getting ovarian cancer during her lifetime is about 1 in 87"—i.e., a risk of 1.15 percent.[43] A relative risk of 1.42 (accepting, arguendo, that Penninkilampi 2018 accurately reflects increased risk) would mean that 1.6 percent of women (1.42/87) with the exposure would be diagnosed with ovarian cancer, not that ***every*** woman with the exposure who develops cancer can attribute it to that exposure.

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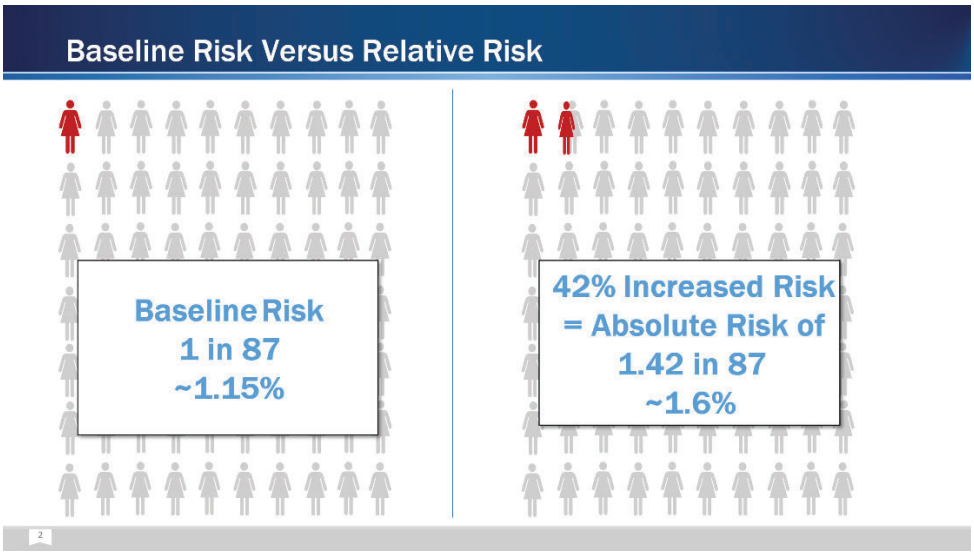
[42] (3/27/24 Siemiatycki Dep. 59:10-60:10; *see also* 3/8/24 Clarke-Pearson Dep. 335:9-24 (Dr. Clarke-Pearson conceding that "increasing your risk by 42 percent does not mean" "you're attributing 42 percent of the cause to something").)

[43] The statistics regarding the absolute risk of a woman getting ovarian cancer are based on the most recent data reported by the American Cancer Society. *See* Key Statistics for Ovarian Cancer, American Cancer Society, https://www.cancer.org/cancer/types/ovarian-cancer/about/key-statistics.html (last revised Jan. 19, 2024).



This alone requires exclusion of Dr. Clarke-Pearson's opinions. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 185 F. Supp. 3d 786, 795-96 (D.S.C. 2016) (excluding specific causation opinion of expert who "interpreted [relative risk ratio] as an ***absolute*** risk, not a ***relative*** risk," and was thereby "off by two orders of magnitude" when considering the relative risk ratios of the plaintiff's risk factors for diabetes).

II. DR. CLARKE-PEARSON DID NOT RELIABLY "RULE IN" TALC AS A CAUSE OF ANY PLAINTIFF'S CANCER OR "RULE OUT" OTHER POTENTIAL CAUSES.

Even if Dr. Clarke-Pearson's opinions could be characterized as the product of a "differential diagnosis," they would still be inadmissible because he did not reliably perform either the "rule in" or the "rule out" stages of that methodology.

A. Dr. Clarke-Pearson Did Not Perform A Reliable Differential Diagnosis With Respect To Ms. Converse.

Dr. Clarke-Pearson's "differential diagnosis" with respect to Ms. Converse is fundamentally flawed, results-oriented and contrary to the scientific literature. Accordingly, it must be excluded.

First, Dr. Clarke-Pearson failed to reliably "rule in" Ms. Converse's alleged use of talcum powder as a possible cause of her ovarian cancer because there is ***no scientific evidence*** tying talc exposure to clear cell ovarian cancer, the specific subtype with which she has been diagnosed. As set forth in defendants' General Causation *Daubert* brief, ovarian cancer is not a single disease; rather, there are many different subtypes of ovarian cancer with different points of origin and causes.[44] The studies that have reported on relative risk by ovarian cancer subtype have overwhelmingly shown ***no*** increased risk of clear cell carcinoma. For example, several meta-analyses (all of which Dr. Clarke-Pearson relies heavily on for his opinion that talc can cause ovarian cancer generally) have reported that the association between talc use and clear cell carcinoma is essentially equal to 1.0—

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[44] (*See* Defs.' Mem. in Supp. of Mot. to Exclude Pls.' Experts' General Causation Ops. at 15-16, 72-74.) Wentzensen & O'Brien, *Talc, Body Powder, and Ovarian Cancer: A Summary of the Epidemiologic Evidence* 163 Gynecol. Oncol. 199, 202 (2021) ("Wentzensen & O'Brien 2021") (Ex. 18 to Davidson Decl.) ("Ovarian cancer is characterized by profound heterogeneity that can be observed in site of origin, genetic susceptibility, somatic mutations, molecular pathways, risk factor associations and morphologic differences.").

meaning no association was found.[45] In addition, a recent case-control study co-authored by Dr. Daniel Cramer (who has served as an expert for plaintiffs in talcum powder litigation), similarly reported a non-statistically-significant association between talc use and clear cell carcinoma.[46] The table below demonstrates that the studies almost unanimously report no statistically significant association between perineal talc use and clear cell carcinoma:[47]

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[45] *See* Berge, *Genital Use of Talc and Risk of Ovarian Cancer: A Meta-analysis*, 27(3) Eur. J. Cancer Prev. 248, 251 (2018) ("Berge 2018") (Ex. 19 to Davidson Decl.) ("No significant associations were detected for . . . clear cell (RR: 0.98; 95% CI: 0.72-1.23) carcinomas."); Taher, *Critical Review of the Association Between Perineal Use of Talc Powder and Risk of Ovarian Cancer*, 90 Reproductive Toxicology 88, 93 (2019) ("Taher 2019") (Ex. 20 to Davidson Decl.) (OR: 0.63; 95% CI: 0.15-2.65 for "clear cell"); Penninkilampi 2018 at 41, 44 (OR: 1.02; 95% CI: 0.75-1.39 for clear cell carcinoma; "[w]e found an increased risk of serous and endometrioid, but not mucinous or clear cell subtypes").

[46] Gabriel, *Douching, Talc Use, and Risk for Ovarian Cancer and Conditions Related to Genital Tract Inflammation*, 28(11) Cancer Epidemiol. Biomarkers Prev. 1835, 1841 tbl. 4 (2019) ("Gabriel 2019") (Ex. 21 to Davidson Decl.) (OR: 1.08; 95% CI: 0.66-1.78).

[47] (Rep. of Michael A. Finan Re: Linda Bondurant ("Finan Rep.") at 66, May 28, 2024 (Ex. 22 to Davidson Decl.).) Cramer 1999 and Rosenblatt 2011 include combined odds ratios for clear cell and endometrioid carcinoma.

Author	Year	Study Type	Clear Cell O.R. (C.I)
Cramer[204]	1999	Meta-Analysis	1.04 (0.67-1.61)*
Wong[205]	1999	Case Control	1.6 (0.6-4.3)
Mills[206]	2004	Case Control	0.63 (0.15-2.64)
Merritt[207]	2008	Case Control	1.08 (0.68-1.72)
Rosenblatt[208]	2011	Case Control	1.53 (0.91-2.57)*
Terry[209]	2013	Pooled	1.24 (1.01-1.52)
Cramer[210]	2016	Case Control	1.01 (0.65-1.57)
Berge[211]	2018	Meta-Analysis	0.98 (0.72-1.23)
Penninkilampi[212]	2018	Meta-Analysis	1.02 (0.75-1.39)
Taher[213]	2019	Meta-Analysis	0.63 (0.15-2.65)
O'Brien[214]	2020	Pooled	1.17 (0.73-1.89)

Dr. Clarke-Pearson contends that the studies are underpowered to detect an association,[48] but plaintiffs have the burden of proof to show an association, not defendants to disprove one. Dr. Clarke-Pearson also points to Terry 2013, the pooled study in the table above, which is the only reported paper finding a statistically significant association between perineal talc exposure and clear cell cancer.[49]

Terry 2013 utilized data from eight datasets, only two of which demonstrated a statistically significant association. The data from one of the two sets that is reported as showing an association between talc use and clear cell

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48 (*E.g.*, 8/27/21 Clarke-Pearson Dep. 542:9-20.)

49 (*Id.* 529:10-17; 3/8/24 Clarke-Pearson Dep. 290:23-291:1 (referencing Terry, *Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls*, 6(8) Cancer Prev. Res. 811, 811 (2013) ("Terry 2013") (Ex. 23 to Davidson Decl.)).

carcinoma come from the same underlying study used in Cramer 2016 (New England Case Control Study), which found ***no increased risk*** of clear cell carcinoma in talc users.[50] In addition, the even more recent Berge 2018 study, which also included the underlying data analyzed in Terry 2013, showed no association between talc use and clear cell carcinoma.[51] When asked at his deposition in 2021, Dr. Clarke-Pearson was not aware of the discrepancies between the Terry 2013 study's underlying data and the data in Cramer 2016.[52] And despite having three more years to attempt to determine why the data are inconsistent, he testified in 2024 that he had not done so.[53]

Second, Dr. Clarke-Pearson also failed to "rule out" Ms. Converse's other potential risk factors for ovarian cancer. "Courts have insisted time and time again that an expert may not give opinion testimony to a jury regarding specific causation if the expert has not engaged in . . . the process of eliminating other possible diagnoses." *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 786

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50 Cramer, *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, 27(3) Epidemiology 334 (2016) ("Cramer 2016") (Ex. 24 to Davidson Decl.).

51 *See* Berge 2018 at 250 (the authors "used the results reported in the meta-analysis by Terry *et al.* (2013) for six of the original eight studies" and used "more extensive results reported in subsequent publications" for the other two studies).

52 (*See* 8/26/21 Clarke-Pearson Dep. 308:1-20 (testifying that he "wasn't aware of" the discrepancy between Terry 2013 and Cramer 2016).)

53 (*See* 3/8/24 Clarke-Pearson Dep. 291:2-292:13.)

(D.N.J. 1996), *aff'd sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 118 F.3d 1577 (3d Cir. 1997) (table); *see also, e.g.*, *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 254 (3d Cir. 2008) (affirming exclusion of specific causation testimony as unreliable, in part because expert "failed to rule out the possibility" of another cause of decedent's death); *Pritchard v. Dow Agro Scis.*, 430 F. App'x 102, 105 (3d Cir. 2011) (affirming exclusion of specific causation expert where expert "failed to adequately address possible alternative causes of [plaintiff]'s cancer"). Thus, "[e]ven if plaintiff's expert[]" can establish a link between exposure to a certain product and plaintiff's alleged injury, "failure to reliably 'rule out' possible causes of plaintiff's" injury would "render[] their methodology unreliable." *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 529, 532 (W.D. Pa. 2003). Dr. Clarke-Pearson's opinions regarding Ms. Converse fail to satisfy this requirement for a host of reasons.

Most importantly, Dr. Clarke-Pearson failed to address Ms. Converse's [redacted], which increases the risk of clear cell carcinoma ***ten-fold***. A population-based study of women with surgically verified endometriosis found that it was strongly associated with clear cell ovarian cancer with an odds ratio of 10.1 (CI = 5.50-16.9),[54] and another recent study reported an even stronger association between endometriosis and clear cell ovarian cancer, with an odds ratio of 11.15

[54] Saavalainen 2018 at 1095; *see also* Noli 2013.

(CI = 6.19-20.10) relative to women without endometriosis.[55] Dr. Clarke-Pearson did not contest this association at his deposition. Nonetheless, Dr. Clarke-Pearson discounted [redacted] as a risk factor for Ms. Converse simply because he believed there was "no evidence of [redacted]" during Ms. Converse's surgery and [redacted] was not "identified on her final pathology report."[56] But Dr. Clarke-Pearson is not a pathologist, and Ms. Converse's pathology report plainly states that her "tumor arose in an [redacted] background."[57] In other words, not only did Ms. Converse have [redacted], ***but that is where her cancer arose.*** Ignoring that compelling evidence is the height of unreliability.

Dr. Clarke-Pearson similarly attempted to dismiss Ms. Converse's use of [redacted] as a possible cause of her ovarian cancer because she used [redacted] for six years,[58] and only "ten years [of] exposure increases" the risk of ovarian cancer.[59] But Ms. Converse testified—and her medical records demonstrate—that she was "on [redacted]."[60] Thus,

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55 Barnard 2024 at E3 tbl. 2.

56 (Converse Rep. at 18; 8/26/21 Clarke-Pearson Dep. 365:16-366:12; *id.* at 272:19-22 ("[T]here was no evidence of [redacted]"); *id.* at 273:1-5 ("T]here is no pathologic evidence that she had [redacted]").)

57 (1/28/21 Schwartz Dep. 31:19-32:4.)

58 (Converse Rep. at 18.)

59 (8/26/21 Clarke-Pearson Dep. 339:8-10.)

60 (Dep. of Hilary Converse 133:24-134:7, Dec. 1, 2020 (Ex. 25 to Davidson Decl.) (emphasis added); *see also* 8/26/21 Clarke-Pearson Dep. 341:10-15.)

Dr. Clarke-Pearson had no factual basis to rule out [redacted] as a potential cause of her disease.

With respect to Ms. Converse's [redacted],[61] Dr. Clarke-Pearson did not even attempt to rule it out as a cause, but instead admitted that this risk factor is a "possible cause" that worked with talc to contribute to Ms. Converse's disease.[62] But Dr. Clarke-Pearson conceded that there is zero evidence to suggest that talc works synergistically to cause cancer.[63]

As other courts have recognized, specific causation opinions are inadmissible where the expert eschews the work of ruling out alternative causes by concluding in summary fashion that all potential causes could have contributed to the plaintiff's disease. *See, e.g.*, *Guerrero v. BP Expl. & Prod. Inc.*, No. 20-0263, 2024 WL 1244796, at *9 (M.D. Fla. Mar. 20, 2024) (excluding specific causation opinion as unreliable because expert failed to "demonstrate serious consideration of [the plaintiff's] risk factors or how much weight to assign their contributory cause"); *In re Lipitor*, 185 F. Supp. 3d at 799 (noting that a specific causation

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61 (8/26/21 Clarke-Pearson Dep. 270:12-15; *id.* 271:3-6 (same); *id.* 277:22-278:8.)

62 (*See* 8/27/21 Clarke-Pearson Dep. 460:13-16 ("Q. You identified a [redacted] as a cause of her ovarian cancer, correct? A. Yes."); *id.* 470:20-22 ("Q. You would agree [redacted] is a cause? A. I think it's a possible cause.").)

63 (3/8/24 Clarke-Pearson Dep. 274:6-10.)

expert "cannot simply opine that all present risk factors are 'substantial contributing factors'"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d 624, 644 (4th Cir. 2018) ("That Lipitor may cause an increased risk of diabetes notwithstanding certain other risk factors is insufficient to conclude that the drug was a substantial contributing factor in an individual patient. To hold otherwise would obviate the need for any specific causation evidence at all."); *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 846 (W.D. Tex. 2005) (rejecting expert methodology that "involves taking a diagnosed condition—cancer—finding all the possible causes of that person's cancer from the universe of potential causes, and declaring all possible causes to be actual causes and but-for causes"). As the Eleventh Circuit put it, a finding that "all possible causes are causes" does not have "general acceptance in the medical and scientific communities." *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1255 (11th Cir. 2010) (citation omitted) (noting that, even where "multiple factors can work together to cause" a disease, an expert is "still required to provide some analysis of why she concluded that, more likely than not, [the agent at issue] substantially contributed to" the occurrence of disease more than other risk factors).

This is all the more true with respect to Ms. Converse because recent scientific literature actually demonstrated no "statistically significant interactions between [redacted]"—one of Ms. Converse's risk factors—"and . . . 10 ovarian

cancer risk factors" (including talc use),[64] undermining Dr. Clarke-Pearson's synergistic hypothesis.[65]

For all of these reasons, Dr. Clark-Pearson failed to conduct a reliable differential diagnosis with respect to Ms. Converse, and his specific causation opinion should be excluded.

B. Dr. Clarke-Pearson Did Not Perform A Reliable Differential Diagnosis With Respect To Ms. Newsome.

Dr. Clarke-Pearson's specific causation opinions regarding Ms. Newsome are unreliable and inadmissible for many of the same reasons.

First, Dr. Clarke-Pearson did not reliably rule in talc as a cause of endometrioid cancer, the specific subtype with which Ms. Newsome was diagnosed. Although Dr. Clarke-Pearson generally asserts that "some studies have suggested endometrioid is increased risk with talcum powder" usage,[66] he fails to offer any scientific evidence whatsoever regarding a *causal* association between talc use and endometrioid cancer (such as through a subtype-specific Bradford Hill analysis).[67] Nor could he, because, as the table below demonstrates, the studies are

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64 Phung, *Effects of Risk Factors for Ovarian Cancer in Women With and Without Endometriosis*, 118(5) Fertil. Steril. 960, 964 (2022) (Ex. 26 to Davidson Decl.).

65 (8/3/24 Clarke-Pearson Dep. 390:19-391:14.)

66 (Dep. of Daniel L. Clarke-Pearson ("2/4/19 Clarke-Pearson Dep.") 133:8-10, Feb. 4, 2019 (Ex. 27 to Davidson Decl.); *see also* Newsome Rep. at 18.)

67 (*See generally* Newsome Rep.)

highly inconsistent, with numerous studies reporting on relative risk by ovarian cancer subtype and finding no statistically significant increased risk of endometrioid cancer,[68] including a recent study co-authored by a plaintiffs' expert in talc litigation (OR: 1.26; 95% CI: 0.94-1.69).[69]

Author	Year	Study Type	Endometrioid O.R.
Cramer[70]	1999	Meta-Analysis	1.04 (0.67-1.61)*
Wong[71]	1999	Case Control	1.40 (0.7-2.7)
Gertig[72]	2000	Cohort	0.91 (0.49-1.87)
Mills[73]	2004	Case Control	1.28 (0.62-2.62)

[68] *See, e.g.*, O'Brien, *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*, 323(1) JAMA 49, 56 (2020) ("O'Brien 2020") (Ex. 28 to Davidson Decl.) ("O'Brien 2020") (OR 1.15; 95% CI: 0.83-1.58)); Gertig, *Prospective Study of Talc Use and Ovarian Cancer*, 92(3) J. Nat'l Cancer Inst. 249, 250-51 (2000) ("Gertig 2000") (Ex. 29 to Davidson Decl.) (noting no "increase in risk for ever talc use for" "endometrioid cancers"); Gates, *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171(1) Am. J. Epidemiol. 45, 50 (2010) ("Gates 2010") (Ex. 30 to Davidson Decl.) (no statistically significant elevations in risk for talc use for endometrioid ovarian cancers (RR 1.06; 95% CI: 0.66-1.69)); Cramer, *Genital Talc Exposure and Risk of Ovarian Cancer*, 81(3) Int'l J. Cancer 351, 354 (1999) ("Cramer 1999") (Ex. 31 to Davidson Decl.) (no association between talc use and endometrioid/clear cell cancers (OR 1.04; 95% CI: 0.67-1.61)).

[69] Gabriel 2019 at 1838, 1841 tbl. 4.

[70] Cramer 1999 at 354 (reported a combined odds ratio for clear cell and endometrioid carcinoma).

[71] Wong, *Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: A Case-Control*, 93(3) Obstet. Gynecol. 372, 374 (1999) ("Wong 1999") (Ex. 32 to Davidson Decl.).

[72] Gertig 2000 at 250-51.

[73] Mills, *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, 112(3) Int'l J. Cancer 458, 461 (2004) ("Mills 2004") (Ex. 33 to Davidson Decl.).

Merritt[74]	2008	Case Control	1.18 (0.81-1.7)
Gates[75]	2010	Cohort	1.06 (0.66-1.69)
Rosenblatt[76]	2011	Case Control	1.53 (0.91-2.57)*
Terry	2013	Pooled	1.22 (1.04-1.43)
Cramer	2016	Case Control	1.38 (1.06-1.8)
Penninkilampi[77]	2018	Meta-Analysis	1.35 (1.14-1.6)
Taher	2019	Meta-Analysis	1.39 (1.05-1.82)
Gabriel	2019	Case Control	1.26 (0.94-1.69)
O'Brien	2020	Pooled	1.15 (0.83-1.58)

In addition, Dr. Clarke-Pearson admitted that no scientific literature shows a 42 percent increased risk for endometrioid ovarian cancer as a result of genital talc use.[78]

Second, Dr. Clarke-Pearson failed to reliably "rule out" other potential causes of Ms. Newsome's endometrioid cancer.

As with Ms. Converse, Dr. Clarke-Pearson entirely failed to address Ms. Newsome's [redacted], which has a strong association with Ms. Newsome's diagnosed cancer—endometrioid. A population-based study reported that women

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74 Merritt, *Talcum Powder, Chronic Pelvic Inflammation and NSAIDs in Relation to Risk of Epithelial Ovarian Cancer*, 122(1) Int'l J. Cancer 170, 172 (2008) ("Merritt 2008") (Ex. 34 to Davidson Decl.).

75 Gates 2010 at 50.

76 Rosenblatt, *Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer*, 22 Cancer Causes Control 737, 740 (2011) (Ex. 35 to Davidson Decl.) (reported a combined odds ratio for clear cell and endometrioid carcinoma).

77 Penninkilampi 2018 at tbl. 2. Notably, Penninkilampi 2018 also noted that the cohort studies demonstrated a non-statistically significant association between endometrioid cancer and talcum powder use (OR 1.09; 95% CI: 0.66-1.8).

78 (3/8/24 Clarke-Pearson Dep. 333:11-19, 334:2-9.)

with surgically verified endometriosis had an odds ratio of 4.72 (CI = 2.75-7.56) of developing endometrioid ovarian cancer,[79] a four-fold increased risk, and another recent study reported an even stronger association between endometriosis and endometrioid cancer, with an odds ratio of 7.96 (CI = 5.59-11.34) relative to women without endometriosis,[80] a seven-fold increased risk. Dr. Clarke-Pearson once again acknowledged that "endometriosis is associated with . . . endometrioid carcinoma."[81] However, despite significant record evidence to the contrary, Dr. Clarke-Pearson insists that Ms. Newsome did not have [redacted].[82] Once again, this indicates a result-oriented approach that ignores the actual medical evidence.

For example, Ms. Newsome's treating physician, Dr. Steren, described the [redacted][83] which is a finding consistent with [redacted].[84] In addition, defendants'

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79 Saavalainen 2018 at 1095.

80 Barnard 2024 at E3 tbl. 2.

81 (8/26/21 Clarke-Pearson Dep. 366:18-23.)

82 (*See* 3/8/24 Clarke-Pearson Dep. 254:19-255:2; Newsome Rep. at 16 (asserting that "[t]here was no evidence of endometriosis on the pathology report" for Ms. Newsome); *id.* at 19 ("Endometriosis—There is no evidence of endometriosis by history, surgical evaluation, or pathologic testing.").)

83 (NewsomeT-WHSMR-00017.)

84 (*See* Rep. of Cheryl Saenz Re: Tamara Newsome at 4, May 28, 2024 (Ex. 36 to Davidson Decl.) ("The [redacted]

(cont'd)

surgical pathologist, Dr. Teri Longacre, performed a histologic analysis of the endometrioid adenocarcinoma in Ms. Newsome's right ovary and identified [redacted] adjacent to that tumor.[85]

Dr. Clarke-Pearson similarly failed to rule out Ms. Newsome's [redacted] risk factor as a cause of her cancer.[86] Dr. Clarke-Pearson initially took the position that [redacted] was not a potential cause based on a single medical record indicating that Ms. Newsome had a BMI of [redacted] at the time of her cancer diagnosis,[87] but after being confronted with multiple other records demonstrating that Ms. Newsome had a BMI of [redacted] at various times prior to her diagnosis,[88] Dr. Clarke-Pearson was forced to concede that [redacted] ***was*** a contributing cause of Ms. Newsome's

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[redacted] .").)

[85] (Rep. of Teri Longacre Re: Tamara Newsome at 14, May 28, 2024 (Ex. 37 to Davidson Decl.) ("The carcinoma is associated with [redacted] (Figures 3 and 4) (slide A8) as well [as] atypical [redacted] (Figures 5-7) (slides A13 and A15).").)

[86] (*See* 8/27/21 Clarke-Pearson Dep. 590:9-14 (identifying "[i]ncreasing age" as a cause of Ms. Newsome's endometrioid ovarian cancer).)

[87] (*Id.* 610:9-20; Newsome Rep. at 19.)

[88] (*See, e.g.*, 3/8/24 Clarke-Pearson Dep. 313:6-15 (agreeing that medical record from March 2015 indicated that Ms. Newsome had a BMI of [redacted]); 8/27/21 Clarke-Pearson Dep. 607:15-608:8 (testifying that he did not consider Ms. Newsome's self-report of a BMI of [redacted] in excluding [redacted] as a cause of Ms. Newsome's cancer).)

cancers.[89] This is significant because the medical literature reports a 37 percent increased risk of developing endometrioid ovarian cancer in individuals with a BMI greater than 30.[90]

Once again, Dr. Clarke-Pearson contends that his inability to rule out Ms. Newsome's other risk factors is not fatal to his specific causation opinions because all of these risk factors worked together "synergistically" with talc to cause Ms. Newsome's cancer.[91] But expert opinions on specific causation that "simply note[] that" other risk factors exist without ruling them out in a scientifically reliable way are inadmissible. *In re Lipitor*, 185 F. Supp. 3d at 794-95. Because Dr. Clarke-Pearson fails to provide any "analysis of why []he concluded that, more likely than

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[89] (3/8/24 Clarke-Pearson Dep. 388:8-12 (testifying he "ha[s] a note to [him]self to" correct Ms. Newsome's BMI); *id.* 321:3-12 (testifying that Ms. Newsome's [redacted] contributed to her developing ovarian cancer).) As noted above, such changes in an expert's opinions when faced with contrary evidence demonstrate the unreliability of those opinions. *See Fireman's Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054, 1059 (8th Cir. 2005) ("[T]his sudden reversal of opinion . . . seriously undermines the reliability of the experts' opinions.").

[90] *See* Olsen, *Obesity and Risk of Ovarian Cancer Subtypes: Evidence from the Ovarian Cancer Association Consortium*, 20(2) Endocr. Relat. Cancer 251 (2013) ("Olsen 2013") (Ex. 38 to Davidson Decl.) (OR 1.37; CI = 1.14-1.64). (*See also* 3/8/24 Clarke-Pearson Dep. 320:9-321:2 (agreeing that Olsen 2013 reported an increased risk of 37 percent associated with BMIs over 30).)

[91] (3/8/24 Clarke-Pearson Dep. 376:6-14 ("Q. And based on your opinion that multiple risk factors can work together or different environmental exposures can work together to cause ovarian cancer, is it your opinion that those things can work synergistically? A. Yes. I mean, I think that -- I understand that from other oncology points of perspectives. Other -- so they can be additive or synergistic, another way for me to put it.").)

not," Ms. Newsome's talc use—as opposed to all of her other admitted risk factors—caused her ovarian cancer, his opinions are unreliable and should be excluded. *Guinn*, 602 F.3d at 1250, 1255.

C. Dr. Clarke-Pearson Did Not Perform A Reliable Differential Diagnosis For Ms. Rausa.

Finally, Dr. Clarke-Pearson's supposed differential diagnosis of Ms. Rausa is just as unscientific as his other opinions.

Most importantly, Dr. Clarke-Pearson's decision to "rule in" talc use as a potential cause of Ms. Rausa's cancer ignores the fact that Ms. Rausa underwent a [redacted] in 1988—approximately ***30 years before*** her ovarian cancer diagnosis[92]—which Dr. Clarke-Pearson admits would have closed the "pathway to her ovaries" that he believes talc must move through to cause ovarian cancer.[93] According to Dr. Clarke-Pearson, ovarian cancer has a latency period of 15 to 20 years following talc exposure.[94] Thus, under Dr. Clarke-Pearson's own reasoning, the "pathway" by which talc could have reached Ms. Rausa's ovary and caused

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92 (Rausa Rep. at 16, 18.)

93 (8/27/21 Clarke-Pearson Dep. 676:20-677:3.)

94 (8/26/21 Clarke-Pearson Dep. 297:12-15.) *See also* Taher 2019 at 97 (suggesting that "the latency period for ovarian cancer is between 15-20 years").

cancer was closed long before the supposed latency period for talc and ovarian cancer.[95]

Dr. Clarke-Pearson also failed to reliably "rule out" other potential causes of Ms. Rausa's cancer ***that he himself identified***—including Ms. Rausa's late [redacted], age and history of [redacted][96]—as well as evidence in Ms. Rausa's medical records of [redacted] and the distinct possibility that Ms. Rausa's cancer has no known cause (i.e., is "idiopathic").

First, Dr. Clarke-Pearson admits that Ms. Rausa had several known risk factors for ovarian cancer that are unrelated to talc—including early [redacted], [redacted] advanced age at time of diagnosis (which Dr. Clarke-Pearson notes "[i]ncreased her risk of having more mutations" capable of causing cancer) and a history of [redacted][97]—that cannot be ruled out as causes of Ms. Rausa's ovarian cancer. Dr. Clarke-Pearson's failure to attempt to rule out any of these causes renders his purported differential diagnosis unreliable and conclusion-driven. *See,*

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95 (*See* Rausa Rep. at 18 (explaining that a [redacted] was performed in 1988, which thereafter likely reduced or eliminated her ovarian talc exposure").) Dr. Clarke-Pearson admitted he is not able to point to any support in the scientific literature for the proposition that Ms. Rausa's latency period could have been 30 years or more. (*See* 3/8/24 Clarke-Pearson Dep. 344:4-346:24.)

96 (*See* 8/27/21 Clarke-Pearson Dep. 675:17-22; Rausa Rep. at 19.)

97 (*See* 8/27/21 Clarke-Pearson Dep. 622:15, 672:8-11, 675:1-15; Rausa Rep. at 17, 19.)

e.g., *In re Lipitor*, 185 F. Supp. 3d at 794-95 (excluding specific causation opinion where the expert failed to "consider and compare the various magnitudes of the risks associated with these various risk factors" and "provide[d] no explanation for how he considered them, if at all, but simply note[d] that" other risk factors exist without ruling them out in a scientifically reliable way); *see also Storey*, 2024 WL 695410, at *7 (excluding expert's differential diagnosis where expert "named several conditions that could affect a patient's ability to heal pressure ulcers" but, "[d]espite her recognition of these possibilities, she at no point ruled out other potential causes to reach her conclusion that . . . negligence caused" the alleged injuries).

Rather than "ruling out" any of Ms. Rausa's other known risk factors, Dr. Clarke-Pearson conceded that "talcum powder isn't the only cause of [Ms. Rausa's] ovarian cancer,"[98] and that each of the other risk factors—along with talc—are "causes" of her ovarian cancer.[99] But, as explained above, specific

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[98] (8/26/21 Clarke-Pearson Dep. 136:8-9; 8/27/21 Clarke-Pearson Dep. 448:13-20 ("[Q. . . [A] woman could be a long-term user of baby powder, could develop ovarian cancer and yet her long-term use of baby powder would not be a cause of her subsequent ovarian cancer, is that fair? . . . . [A.] I think it's fair to say it's possible."); 8/26/21 Clarke-Pearson Dep. 216:25-217:7 (opining that because ovarian cancer is "multifactorial[,]" "it's very difficult for anybody to specifically say one thing," like talc, "caused ovarian cancer").)

[99] (*See* 8/27/21 Clarke-Pearson Dep. 675:17-672:2 ("Q. But each one of those factors, age, talc, [redacted], [] and [redacted] were a cause of Ms. Rausa's ovarian cancer? [A.] Yes.") (objection omitted); *id.* 663:11-17 ("[Q.] [I]t sounds like you *(cont'd)*

causation opinions are inadmissible where the expert eschews the work of ruling out alternative causes by concluding in summary fashion that all potential causes could have contributed to the plaintiff's disease. *See, e.g.*, *In re Lipitor*, 185 F. Supp. 3d at 799; *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d at 644; *Cano*, 362 F. Supp. 2d at 846. As the Eleventh Circuit has explained, causation experts "cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development" because a finding that "all possible causes are causes" does not have "general acceptance in the medical and scientific communities." *Guinn*, 602 F.3d at 1255 (citation omitted) (noting that, even where "multiple factors can work together to cause" a disease, an expert is "still required to provide some analysis of why she concluded that, more likely than not, [the agent at issue] substantially contributed to" the occurrence of disease more than other risk factors).

Dr. Clarke-Pearson's opinions are all the more egregious because he does not—and cannot—point to any scientific literature suggesting that talc works synergistically with other risk factors to cause ovarian cancer.[100] Nor does he even

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are of the view, here in your deposition, that Ms. Rausa's [redacted] was a cause of her ovarian cancer, is that right? A. It was one of the causes, yes."); 672:8-13 ("[Q.] Age was a cause of Ms. Rausa's ovarian cancer, correct? . . . A. Yes."); 675:11-15 ("Q. So would you consider the fact that Ms. Rausa [redacted] to also be a cause of her ovarian cancer? [A.] Yes.") (objection omitted).)

[100] (3/8/24 Clarke-Pearson Dep. 274:6-10.)

attempt to identify the "exact contribution" of talc or any other risk factor[101] to Ms. Rausa's cancer. This omission is notable because one of Ms. Rausa's risk factors—a history of [redacted]—has been shown in some scientific literature to increase a woman's risk of ovarian cancer.[102] For these reasons, Dr. Clarke-Pearson fails to provide any "analysis of why []he concluded that, more likely than not," Ms. Rausa's talc use—as opposed to all of her other risk factors—caused her ovarian cancer, rendering his opinions inherently unreliable. *See Guinn*, 602 F.3d at 1250, 1255.

Second, to the extent Dr. Clarke-Pearson purports to rule out a few specific risk factors—including [redacted]—as causes of Ms. Rausa's cancer, his analysis is contrary to the facts in the record. For example, according to Ms. Rausa, she "was between 55 and 56" when she

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[101] (8/26/21 Clarke-Pearson Dep. 217:25-218:10; 8/27/21 Clarke-Pearson Dep. 676:4-9 (failing to "ascribe a weight" or "a percentage" to the amount each risk factor "contributed to Ms. Rausa's ovarian cancer").)

[102] Gonzalez, *Douching, Talc Use, and Risk of Ovarian Cancer*, 27(6) Epidemiology 797, 797 (2016) ("Gonzalez 2016") (Ex. 39 to Davidson Decl.) ("douching at baseline was associated with increased subsequent risk of ovarian cancer" (HR 1.8; 95% CI: 1.2-2.8)); Chang, *Use of Personal Care Product Mixtures and Incident Hormone-Sensitive Cancers in the Sister Study: A U.S.-Wide Prospective Cohort*, 183 Environ. Int'l 1, 5 (2024) (Ex. 40 to Davidson Decl.) (noting a "a stronger positive association between douche and ovarian cancer incidence" (HR 1.31; 95% CI: 1.06-1.63)).

went through [redacted],[103] which Dr. Clarke-Pearson concedes would qualify as late [redacted] that "increased Ms. Rausa's risk for ovarian cancer."[104] But Dr. Clarke-Pearson nonetheless claims he can "rule out" late menopause because there are conflicting reports in Ms. Rausa's medical records regarding her age at [redacted]—47 to 48 and 55 to 56—and Dr. Clarke-Pearson subjectively "went with" the earlier of the two age ranges listed, ignoring the age confirmed by Ms. Rausa herself.[105] Dr. Clarke-Pearson similarly acknowledged that Ms. Rausa has "a number of [medical] records . . . noting [redacted]" and that he would consider [redacted] to be a risk factor for ovarian cancer.[106] But after he "reviewed this report and then . . . reviewed the rest of her story," Dr. Clarke-Pearson simply decided those records must be wrong and that the treating radiologist who interpreted Ms. Rausa's ultrasound must have "misinterpreted" the results.[107]

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103 (Dep. of Pasqualina Rausa 80:20-22; 98:4-12, Jan. 27, 2021 (Ex. 41 to Davidson Decl.) (Ms. Rausa testifying that "[t]he reason why I remember that is because my sister told me [redacted] and I compared mine with hers" and "I know it was between 55 and 56.").)

104 (8/27/21 Clarke-Pearson Dep. 624:20-625:10.)

105 (*Id.* 622:19-623:1.)

106 (*Id.* 667:16-24, 671:7-9.)

107 (*Id.* 665:14-666:22, 667:3-13.)

In short, to the extent Dr. Clarke-Pearson made any effort to "rule out" other possible causes of Ms. Rausa's cancer, he did so based on factual assumptions and subjective interpretations that are contrary to the record. *See Elcock v. Kmart Corp*., 233 F.3d at 734, 756 (3d Cir. 2000) (expert opinion was improperly admitted when expert made several assumptions not supported by the record, such as "questionable assumptions" about the plaintiff's life expectancy, because "[i]gnoring 'the real world of'" the plaintiff rendered the opinion inadmissible).

Third, Dr. Clarke-Pearson's specific causation opinion with respect to Ms. Rausa is also unreliable because he did not account for the fact that most high grade serous ovarian cancer is idiopathic. As several courts have recognized, failure to evaluate the possibility that unknown causes are to blame for a plaintiff's injuries renders a specific causation analysis unreliable. *See, e.g.*, *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016) (upholding trial court's exclusion of expert who failed to reliably rule out idiopathic causes); *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig*., MDL No. 2848, 2023 WL 6465837, at *7 (E.D. Pa. Oct. 4, 2023) (expert's failure to eliminate idiopathic causes of the plaintiff's headache disorder rendered a differential diagnosis too unreliable to be admitted); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014) (expert "omitted consideration of idiopathic causes for" the plaintiff's injury, "rendering his differential diagnosis unreliable"); *Tamraz*, 620 F.3d at 675 (expert

opinion speculative where expert did not consider idiopathic causes, especially because "unknown (idiopathic) causation . . . currently accounts for the vast majority of Parkinson's Disease cases, making it impossible to ignore and difficult to rule out"). Indeed, as the U.S. Court of Appeals for the Eighth Circuit has explained, "[w]here the cause of the condition is unknown in the majority of cases, [an expert] cannot properly conclude, based upon a differential diagnosis," that the plaintiff's exposure to the substance was "the most probable cause" of her injury. *See Bland v. Verizon Wireless (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008).

The same is true here. In 2021, Dr. Clarke-Pearson readily admitted that "[w]e can't identify all the things that cause mutations" that result in ovarian cancer.[108] Indeed, Dr. Clarke-Pearson even identifies "unknown factors" as potential "causes of Ms. Rausa's ovarian cancer."[109] Yet, when asked how he was able to rule out idiopathic causes of a plaintiff's cancer, all Dr. Clarke-Pearson could do was reiterate his unscientific and results-oriented view that "talcum powder . . . increase[s] risk of ovarian cancer" and therefore "was one of the causes, not the only cause."[110] Needless to say, simply asserting that talc is a

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[108] (8/26/21 Clarke-Pearson Dep. 221:6-13; *see also, e.g.*, *id.* 295:6-12 ("Q. And what you're saying is in any individual woman, we don't know all of the causes that come together to cause the mutation that cause [ovarian cancer]? [A.] Yes. We know some of the causes, but not always all of them.") (objection omitted).)

[109] (8/27/21 Clarke-Pearson Dep. 671:20-23.)

[110] (8/26/21 Clarke-Pearson Dep. 222:11-223:13.)

possible cause of cancer is insufficient to rule out the possibility that Ms. Rausa's cancer was entirely idiopathic. *See Hall v. Conoco Inc.*, 886 F.3d 1308, 1314-15 (10th Cir. 2018) (upholding exclusion of expert whose "failure to rule out idiopathic causes" of the plaintiff's acute myeloid leukemia was "a fatal error tainting the differential diagnosis"); *Milward*, 820 F.3d at 476 (upholding exclusion of expert testimony based on a differential diagnosis in part because the disease at issue has a large number of idiopathic cases). For this reason, too, Dr. Clarke-Pearson's specific causation opinions should be excluded. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1343 (11th Cir. 2010) (expert "failed to apply the differential diagnosis methodology reliably" where he did not explain why idiopathic causes of disease could be ruled out).

III. DR. GODLESKI'S PURPORTED FINDINGS CANNOT SALVAGE DR. CLARKE-PEARSON'S UNRELIABLE OPINIONS.

Lastly, Dr. Clarke-Pearson cites to the purported pathologic findings of another plaintiffs' expert, Dr. Godleski, as "further evidence to support [his] causation opinions."[111] According to Dr. Clarke-Pearson, Dr. Godleski found particles consistent with talc in certain samples of plaintiffs' tissue. But as Dr. Clarke-Pearson conceded, "the presence of talc particles . . . in pathology" was

[111] (*See* Rausa Rep. at 18; Newsome Rep. at 18; Converse Rep. at 17.)

"not a requirement" for him to render a causation opinion.[112] Indeed, he did not even look at Dr. Godleski's report for Ms. Converse until after he arrived at his opinion that talc use caused her clear cell carcinoma.[113]

In any event, Dr. Godleski's findings cannot feasibly support any reliable causation opinion because, as Dr. Clarke-Pearson was forced to concede, Dr. Godleski did not locate any particles consistent with talc in Ms. Converse or Ms. Rausa's tissues that actually had cancer.[114] And although Dr. Godleski purportedly found a single particle consistent with talc in Ms. Newsome's right ovary—the situs of her cancer—he also located 30 particles consistent with talc that were in cancer-free tissues.[115]

Nor did Dr. Clarke-Pearson consider whether the numerous non-talc particles Dr. Godleski observed in plaintiffs' tissue samples could have been agents that potentially cause ovarian cancer. For example, Dr. Godleski found 515

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112 (*See* Rausa Rep. at 18; Newsome Rep. at 18; Converse Rep. at 17.)

113 (8/26/21 Clarke-Pearson Dep. 239:2-11; *id.* 271:14-21.)

114 (*See* 8/26/21 Clarke-Pearson Dep. 271:22-272:15 ("Q. Did Dr. Godleski find talc in [Ms. Converse's] tissues that had cancer? A. Not [in] the tissues that he studied."); 8/27/21 Clarke-Pearson Dep. 626:7-627:4 ("The two particles of what Dr. Godleski claimed to be talc were not found in any of Ms. Rausa's tissue that was associated with cancer, is that right? . . . . Yes, I believe they're in lymph nodes.").)

115 (Rep. of John Godleski Re: Tamara Newsome ("Godleski *Newsome* Rep.") at 4, June 24, 2021 (Ex. 42 to Davidson Decl.); Newsome Rep. at 14.)

particles in Ms. Rausa's tissue samples, but identified only two of them as particles consistent with talc.[116] Of the remaining particles, Dr. Godleski noted that 158 had constituents indicative of exogenous materials.[117] Dr. Clarke-Pearson admitted that he did not know "what the 158 exogenous materials or particles were" and that it was "certainly possible" that "any 158 of them . . . played a role in Ms. Rausa's development of ovarian cancer."[118] In addition, Dr. Clarke-Pearson failed to consider whether the 791 non-talc-like particles Dr. Godleski observed in Ms. Newsome's tissue samples could have been agents that potentially cause ovarian cancer.[119]

In any event, there is no reliable scientific evidence to support a conclusion that the mere presence of alleged talc particles in an ovarian cancer patient's tissue is evidence that the cancer was caused by talc. Indeed, Dr. Godleski himself co-authored a paper in which he expressly ***disclaimed*** any suggestion that the presence of talc in the body is enough to establish "a causal relationship between

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116 (8/27/21 Clarke-Pearson Dep. 630:19-631:13; *see also* Rep. of John Godleski Re: Pasqualina Rausa at 4, June 21, 2021 (Ex. 43 to Davidson Decl.); Dep. of John Godleski 142:9-15, Mar. 29, 2024 (Ex. 44 to Davidson Decl.).)

117 (Dep. of John Godleski 110:6-17, Mar. 28, 2024 (Ex. 45 to Davidson Decl.).)

118 (8/27/21 Clarke-Pearson Dep. 631:20-632:9.)

119 (*Id.* 581:9-22.)

ovarian cancer and talc use."[120] *See In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018), *aff'd*, 982 F.3d 113 (2d Cir. 2020) ("[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study.") (quoting *In re Accutane Prods. Liab*., No. 8:04-MD-2523-T-30TBM, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd*, 378 F. App'x 929 (11th Cir. 2010)). Other published literature is in agreement, including a study noting that talc particles were observed in the ovaries "to a similar extent" with "both 'exposed and unexposed' subjects," none of whom had ovarian cancer.[121] As a result, Dr. Godleski's findings cannot provide any support for Dr. Clark-Pearson's unreliable causation opinions.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude Dr. Clarke-Pearson's specific causation opinions with respect to Ms. Rausa, Ms. Converse and Ms. Newsome.

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[120] (*See* Defs.' Mem. in Supp. of Mot. to Exclude Ops. of Dr. John Godleski at 12 (quoting Cramer, *Presence of Talc in Pelvic Lymph Nodes of a Woman With Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110(2) Obstetrics & Gynecology 498, 500 (2007) ("Cramer 2007")) (Ex. 46 to Davidson Decl.).)

[121] (*See id.* at 19 (quoting Heller, *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, 174(5) Am. J. Obstet. Gynecol. 1507, 1508 (1996)) (Ex. 47 to Davidson Decl.).)

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